PETER D. FOX
WNA Executive Director
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WISCONSIN NEWSPAPER ASSOCIATION

...world's oldest press association, established 1853

March 10, 2009

To: Members of the Assembly Committee on Public Health
From: Peter D. Fox, Executive Director, Wisconsin Newspaper Association

Subject: 2009 Assembly Bill 56

Thank you for the opportunity for the Wisconsin Newspaper Association (WNA) to testify at this public hearing on 2009 Assembly Bill 56 that would prohibit advertising for prescription drugs in Wisconsin. We note this third resurrection of an identical bill since the 2005 legislative session.

Constitutionally, AB 56 – like its predecessors – has fundamental, fatal flaws. The bill seeks to ban communication in Wisconsin which is legal and protected in every other state and territory of the United States. As written, the bill would forbid Wisconsin publishers and broadcasters from printing or airing what others could freely circulate in our state. If enacted, this bill would create impossible, logic-defying situations. For example, would Wisconsin publishers be able to accept national or regional newspaper inserts – the Sunday magazine supplement is just one product that comes to mind? What about the not-uncommon situation of advertising inserts printed in Illinois, Iowa or Minnesota but circulated in Wisconsin newspapers?

Meanwhile, under this provision an advertisement may be circulated by print or over-the-air broadcast if it emanates from an out-of-state source such as a national television or radio network, or from a publication published outside Wisconsin – such as *USA Today*, the *Chicago Tribune*, *The Wall Street Journal*, *New York Times*, *Time* or *Newsweek* magazine or a plethora of other publications. Curiously, the bill is silent on such modern communications means as the Internet and cable television.

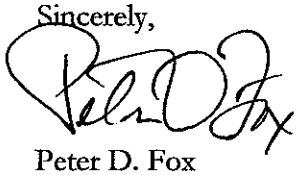
WNA readily concedes the subject of prescription drug advertising – particularly for the so-called "boutique" drugs – and how it affects overall prescription drug pricing is a matter of great public interest. We understand much of the concern of the legislators who bring this proposal forward. WNA member newspapers across the state for years have published news stories to inform the public about how the cost of drug advertising affects consumer pricing.

AB-56 has a direct parallel in an embarrassing sequence for the Florida legislature in 1987 when it enacted a in-state only advertising tax only to reverse course six months later. In that situation, Florida imposed a sales tax on in-state advertising. Advertising that was broadcast and delivered into Florida from other states was not taxed. To distinguish between in-state and out-of-state advertising became an impossible task and the legislature was forced to backpedal.

The lesson here is that state legislatures cannot enact laws in isolation from what occurs in other states. Additionally it is important to understand that individual states cannot restrict speech protected by the First Amendment. We also note that in 1951 Congress gave the U.S. Food and Drug Administration jurisdiction for prescription drug advertising.

In summary, the Wisconsin Newspaper Association respectfully recommends that the committee reject AB-56 because of its extensive constitutional and jurisdictional flaws.

Sincerely,



Peter D. Fox
Executive Director

Direct to Consumer Advertising (DTCA) of Prescription Drugs

Jonathan Knoche
Wisconsin Medical Society
UW School of Medicine and Public Health

Perceived benefits of DTCA

1. Patient education→ informed patients are more involved in their healthcare.
2. Tackling under-treatment and getting people to visit their doctor.
3. Better outcomes→ improved economic value
4. Improved drug treatment compliance
5. Improved physician-patient relationship (Auton 25)

Claimed harmful effects of DTCA

1. Marketing is for profit, not consumer education and health.
2. Leads to increased drug budget costs
   - DTCA increases demand and price of drugs.
   - Health expenditures have grown more rapidly for prescription drugs than for any other type of medical care. (Doonan 1, 5)
3. Misleads patients if advertisement is unbalanced in disclosing benefits versus side-effects.
4. Increased patient risk from new drugs (e.g. Vioxx; Celebrex).
5. Damages the doctor-patient relationship.
6. Increases pressure on doctor visits and workload of patients.
7. Medicalizes conditions common to human existence and aging (Auton 25).

Physician survey conducted by the FDA regarding the impact of DTCA on the physician-patient relationship.

- Prescribers respond to patient requests for a prescription 75% of the time.
- Beneficial effects doctors reported: better discussion with patient; patient more aware of treatments
- Problems doctors encountered: time to correct misconceptions; drug not needed/did not have condition.

Physicians reported that patients are aware: That the drug is available only by prescription, of possible benefits and positive effects
However, patients do not have a clear idea of: Possible risks and negative effects, who should not use the drug.

WMS Position

DRU-011: WMS supports efforts to control DTCA of prescription drugs and AMA actions to strengthen federal efforts to more effectively regulate such advertising. (HOD, 0405)

Takeaways

1. <u>DTCA increases healthcare costs</u>
   - Drug companies are an industry that use DTCA to increase profits
   - Most of what they sell is NOT innovative (77% are "me-too" drugs)

2. <u>DTCA can harm the public health</u>
   - New drugs have less history, unknown side effects (e.g. Vioxx)

3. <u>DTCA can impair physician-patient relationship</u>
   - Should be free from outside influence and put patient well-being at the forefront

4. Support measures that retain the benefits of DTCA but eliminate the harmful side effects

5. Protect the health of the people of Wisconsin and vote in support of AB-56.

from Jonathan Knowles

Prescription Drug Marketing:
What Consumers Need to Know

Pharmaceutical companies spend $5 billion a year selling prescription drugs to consumers. *Direct-to-consumer* (DTC) promotion of medications includes advertisements in newspapers and magazines, TV ads, coupons, and industry-funded websites, newsletters, and patient support services.

Turn on your television and you are likely to catch a commercial for the latest sleep aid or depression medication featuring happy, attractive people. On average, an adult in the U.S. is exposed to 100 minutes of DTC television ads for every minute spent seeing a doctor. DTC promotion focuses only on a handful of drugs – the ones that are most profitable. Marketing dollars are primarily spent on the newest, most expensive drugs, for which some risks may not yet be known.

In the United States, direct-to-consumer ads are regulated by the Food and Drug Administration (FDA). However, the FDA does not approve ads before distribution and lacks the staff to monitor the accuracy of all DTC ads. When the FDA learns of a misleading ad, the agency can complain in writing and require the company to stop using the ad. But such letters are rare, and it may take many months for the FDA to force a drug company to stop circulating a misleading drug ad.

Television and radio ads for drugs don't provide consumers with all known risks. The drug companies are not required to provide such information as long as the ad refers the consumer to an internet site, a print advertisement, a toll-free telephone number, or a health care provider. The Food and Drug Administration (FDA), which regulates prescription drugs, does not regulate so-called help-seeking ads, which sell diseases rather than drugs.

Branding Conditions

Inventing – or reinventing – diseases and conditions enables drug companies to market diseases under the guise of education; "disease awareness" ads do not mention any drug risks. Osteopenia, or low bone mass, is one example of an invented disease. Real conditions are sometimes renamed in order to increases diagnoses or to link a specific diagnosis to a specific drug. Renamed conditions include heartburn (renamed GERD, for gastroesophageal reflux disease), incontinence (now Overactive BladderSyndrome), impotence (now Erectile Dysfunction), and shyness (now Social Anxiety Disorder). Restless legs syndrome, a real but rare condition, was redefined in order to expand the market for a treatment. "Branding" a condition may be done by a company with the best-selling (or only) drug for a condition. Sometimes companies work together to brand a condition to create as large a market as possible for a class of drugs. These advertisements, disguised as education, are designed to drive worried consumers into physicians' offices for diagnoses – and treatments - that may be unnecessary.

Advertised Drugs May Not Be the Best For You

In the first half of 2005, pharmaceutical manufacturers spent more on media campaigns than any other industry except the automobile industry. Studies show that when a patient requests a specific drug, doctors may prescribe it even if the drug is not in the patient's best interest. Your doctor, not a drug company, should be deciding about your diagnosis and treatment. You may not need a drug at all.

If you do need a drug, the advertised drug may not be best for you. Consumer Reports Best Buy Drugs found the four best drugs for treating high blood pressure to be *generic* drugs, not costly brand-name products. The most-promoted drugs are usually the newest drugs, about which the least is known. Half of all drug withdrawals and black-box warnings (the FDA's most severe warning

about adverse effects) take place within the first two years a drug is on the market. New drugs should be prescribed cautiously until more is known about their safety; drug marketing encourages reckless use of drugs. Consider asking your doctor to prescribe a time-tested drug. More safety information is available on drugs that have been available for seven years or more. (See our factsheet on generic drugs).

Relationship Marketing

DTC ads are only one aspect of DTC promotion, which now includes a heavy dose of customer relationship marketing – services meant to increase loyalty to a brand. Examples of industry-funded programs include "In Your Corner," a support program for women living with breast cancer from the manufacturers of Arimidex, the "Us Against Athero" campaign from the makers of Crestor, and the "GetQuit" program from the manufacturers of Chantix. Under the guise of education, these programs are designed to increase sales of specific drugs. Industry is also experimenting with product placement, including Zoloft in the movie *The Sixth Sense* and Nuvaring in the TV show *Scrubs*.

The Bottom Line

Prescription drugs can be important for our health, but only if they are the right drugs, used the right way. Choosing treatments that affect your health is too important to leave in the hands of marketers. Prescribers and consumers must rely on unbiased sources of information on drugs. Don't rely on industry for drug information or personal support. Be skeptical of new diseases. When a prescription is called for, don't ask your health care provider for advertised drugs. Instead, ask if an older, classic drug is available.

Good sources of unbiased information include:

Consumer Reports Best Buy Drugs (Consumers Union)
http://www.consumerreports.org/health/best-buy-drugs/index.htm

RxFacts Independent Drug Information Service http://www.rxfacts.org

Worst Pills, Best Pills http://www.worstpills.org/

The Cochrane Collaboration http://www.cochrane.org

Agency for Health Care Research and Quality (AHRQ) http://www.ahrq.gov

For more sources, see Drug Information at http://pharmedout.org/topic.htm#druginfo

The National Women's Health Network—one of the few consumer advocacy groups that takes no money from pharmaceutical companies—improves the health of all women by developing and promoting a critical analysis of health issues in order to affect policy and support consumer decision-making.

PharmedOut.org is an independent, publicly funded project that empowers physicians to identify and counter exposes inappropriate pharmaceutical promotion practices.

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Brownfield ED, Bernhardt JM, Phan JL, Williams MV, Parker RM. Direct-to-consumer drug advertisements on network television: an exploration of quantity, frequency, and placement. J Health Commun. 2004; 9(6):491-497.

Gellad ZF, Lyles KW. Direct-to-consumer advertising of pharmaceuticals. Am J Med 2007;120:475-480.

Ta S, Frosch DL. Pharmaceutical product placement: simply script or prescription for trouble? J Public Policy Marketing 2008;27(1):98-106.

Statement PhRMA

In Opposition to AB 56

March 4, 2009

Position: PhRMA opposes Wisconsin AB 56 which would prohibit pharmaceutical companies from disseminating direct-to-consumer (DTC) advertising in Wisconsin. The Food and Drug Administration (FDA) regulates DTC advertisements which preempts state laws.

The Pharmaceutical Research and Manufacturers of America (PhRMA) believes that current Food and Drug Administration (FDA) policies effectively regulate direct-to-consumer advertisements (DTCA). Last year alone, drug manufacturers invested more than $58.8 billion in research and development of new medicines; whereas, direct to consumer advertising accounts for less than 2 percent of the total spending for prescription medicines in the U.S.[1,2]

DTCA Provides Valuable Educational Information to Patients

DTC advertising's overarching purpose is to inform and educate patients about treatable conditions, symptoms of illness, and available therapies. Research shows that communication with the general public about approved drug products through print, broadcast, and electronic media encourages productive dialogue between patients and their physicians. Nearly one in five patients reported speaking to a physician about a condition for the first time because of a DTC ad.[3] Furthermore, "[DTC advertising] can empower consumers to manage their own health care by providing information that will help them, with the assistance of their doctors, to make better informed decisions about their treatment options."[4]

Lack of compliance is a critical problem in achieving effective medical care. The World Health Organization states, "Poor adherence to long-term therapies severely compromises the effectiveness of treatment, making this a critical issue in population health both from the perspective of quality of life and of health economics."[5] According to Prevention Magazine, DTC ads encourage compliance with physician-prescribed treatment regimens. For example, a RXRemedy and Pfizer study found that patients who involve themselves in their health care by asking their doctor about a prescription drug they saw in a DTC advertisement are more likely to take their medication than those who do not. Furthermore, arthritis patients who have seen a DTC ad are 75 percent more likely to stay on their medication and patients treated for depression are 37 percent more likely to stay on their medication.[6]

DTCA Does Not Replace the Doctor-Patient Relationship

The physician or prescriber evaluates the benefits and risks contained in a drug's approved labeling, determines if the drug is appropriate for that patient, and gives the patient specific instructions and warnings specific to their condition when the drug is prescribed. The physician-patient relationship is essential to all medical treatment and can never be replaced by advertising. In fact, the National Medical Association (NMA) found that "Doctors are

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[1] Burrill & Company, analysis for Pharmaceutical Research and Manufacturers of America, 2007 (includes PhRMA research associates and non-members).

[2] Harvard University and Massachusetts Institute of Technology, study of direct-to-consumer advertising (Washington, DC: The Henry J. Kaiser Family Foundation, June 2003).

[3] K. Aikin, *Direct-to-Consumer Advertising of Prescription Drugs: Patient Survey Results,* 19 September 2002, http://www.fda.gov/cder/ddmac/Presentations/kithmcc2002out/sld001.htm (accessed 6 August 2004).

[4] Federal Trade Commission, *op. cit.*

[5] World Health Organization, *Adherence to Long-Term Therapies: Evidence for Action*, 2003, http://www.who.int/chronic_conditions/adherencereport/en (accessed 8 September 2004).

[6] Pfizer Inc and RxRemedy, Inc., *Impact of DTC Advertising Relative to Patient Compliance,* June 2001, http://www.pfizer.com/are/about_public/mn_about_dtcadsdoc. html (accessed 11 August 2004).

finding that [DTC] ads are helping patients talk to [doctors] about medical conditions they're at risk for...We must view [DTC ads] as one of the several tools that are potentially beneficial to the physician-patient dyad."

The FDA Oversees Prescription Drug Advertising

Unlike other types of advertisements, including advertisements from managed care companies, pharmaceutical DTC advertising must meet strict regulatory standards enforced by the federal FDA. Section 301 of the Federal Food, Drug, and Cosmetic Act (FDCA) prohibits the introduction into commerce or receipt in interstate commerce of any food, drug, device, or cosmetic that is "misbranded." Section 502(n) of the Act provides that a prescription drug shall be deemed misbranded unless all advertisements for that drug contain a "true statement" of: (1) the established (generic) name of the drug; (2) the ingredients of the drug; and (3) a brief summary relating to side effects, contraindications, and effectiveness. Such advertising must be truthful, present a fair balance of benefits and risks, and note that the medicine can only be purchased with a prescription. Furthermore, federal law requires that advertisements (both published and broadcast) include information about the major side effects and risks associated with the advertised drugs.[7]

Manufacturers must submit all advertising for a new medicine to the FDA for review prior to using the advertising and many manufacturers ask FDA to review advertising for older drugs. FDA has a variety of methods to enforce its regulation of advertising of prescription drugs, including requiring the manufacturer to conduct corrective advertising.

Direct-To-Consumer Advertising Is Protected Commercial Speech

The landmark U.S. Supreme Court decision, Central Hudson Gas & Electric Corp. v. Public Serv. Commission Of New York, established a four-part test to be applied by courts in determining the constitutionality of commercial speech restrictions.[8] First, the government may prohibit commercial speech only if the speech is inherently false or misleading or proposes an unlawful transaction. Second, the government must establish that it has a "substantial" interest in restricting speech. Third, the government must establish that its restriction directly furthers its objective – in other words, that the restriction "advances the Government's interest in a direct and material way." Fourth, the government must demonstrate that the governmental restriction is no more extensive than necessary to achieve the governmental interest. Not only are advertisements for prescription medicines not false or misleading, they are among the most regulated advertisements of any industry.

PhRMA Guiding Principles for DTC

PhRMA member companies take their responsibility to fully comply with FDA advertising regulations seriously. Patients, health care providers and the general public expect drug makers to do more than just meet these exacting legal obligations. To meet these expectations, PhRMA developed its own Guiding Principles on Direct-to-Consumer Advertising of Prescription Medicines to go further than required in regulating DTC advertising.

For the reasons set forth above and in an effort to provide as much information as possible for patients and physicians to together make informed decisions, PhRMA respectfully opposes Wisconsin AB 56.

[7] 21 CFR 202.1(l)1

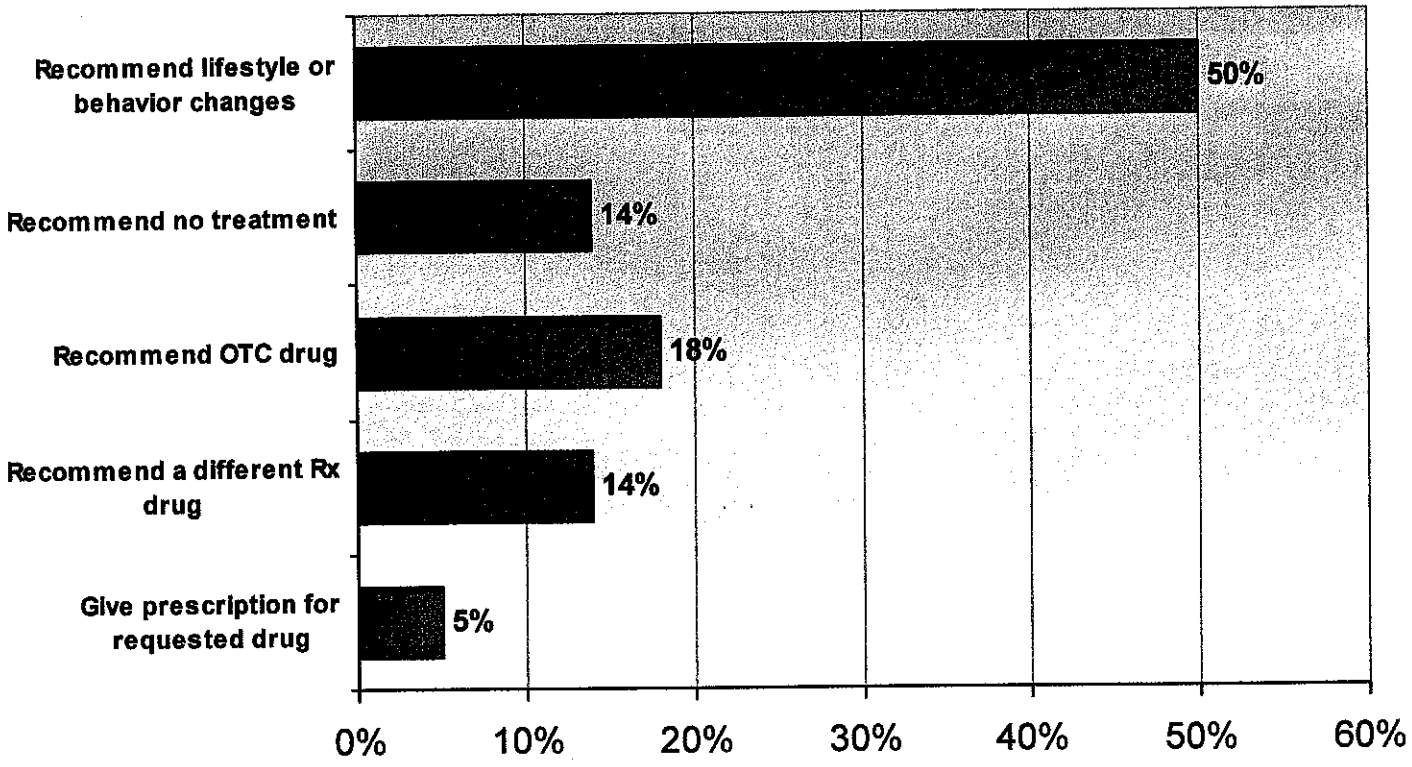
[8] Central Hudson Gas & Elec. Corp. v. Public Serv. Commission, 447 U.S. 557 566 (1980).

Physicians' Response to Patient Requests

PhRMA

Over three-fourths (78%) of primary care physicians, when asked for a prescription for a specific brand name drug, felt little or no pressure to prescribe a medicine[1]

When asked by a patient about a specific treatment, physicians frequently...[2]



A 2006 Government Accountability Office (GAO) report found that 2–7% of consumers who saw DTC advertising requested and ultimately received a prescription for the advertised drug.[3]

Sources: [1]K. Aikin et al, *Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs – Summary of FDA Survey Research Results, Final Report* (U.S. Department of Health & Human Services, FDA, Center for Drug Evaluation and Research 2004); [2]Kaiser Family Foundation, "National Survey of Physicians, Toplines," 2006; [3]GAO, *Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising*, 2006.

MMAC

Metropolitan Milwaukee
Association of Commerce

DATE: **MARCH 10, 2009**

TO: **THE ASSEMBLY COMMITTEE ON PUBLIC HEALTH**

FROM: **STEVE BAAS, GOVERNMENT AFFAIRS DIRECTOR**
METROPOLITAN MILWAUKEE ASSOCIATION OF COMMERCE

RE: **ASSEMBLY BILL 56**

On behalf of the Metropolitan Milwaukee Association of Commerce (MMAC) and its nearly 2000 member companies, I am appearing today in opposition to Assembly Bill 56, prohibiting advertising for prescription drugs.

AB 56 is a troubling impingement on the free speech rights of companies disseminating information about legal products to consumers. This bill purports to restrict those rights in the name of public health and safety. However, that presupposition ignores the fact that the public's health and safety with regard to prescription drug products is already given twin layers of protection. First, from the fact that these drugs have been approved as safe after rigorous scrutiny by the United States Food and Drug Administration, and second, from the fact that these products can only be obtained via a prescription from a licensed medical practitioner.

In addition to this bill being unnecessary from a public safety standpoint for the reasons noted above, this bill is also troubling in its attitude toward consumers. We live in an information age. From niche media dealing with medical topics, to internet tools like WebMD, consumers have unprecedented access to medical information. Today, more than ever before, consumers are equipped with the tools to investigate and evaluate the claims made in drug advertisements. AB 56 appears to proceed from a premise that consumers are not intelligent enough to rationally use those tools in making health care decisions that affect their lives and the lives of their loved ones. We believe that premise is misguided. In short, if we trust the public to exercise sound judgment in the face of advertising for everything from shoes to cars to political candidates, it is incongruous to imply, as AB 56 does, that the public is not able to exercise an equal level of judgment with regard to drug advertisements.

Thank you for this opportunity to share these concerns with you. I respectfully encourage you to oppose AB 56.

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PHARMACY
SOCIETY OF
WISCONSIN

*"Leading Our Profession
in a Changing
Health Care Environment"*

Members of the Assembly Committee on Public Health

Testimony by the Pharmacy Society of Wisconsin on Assembly 56

Tuesday, March 10, 2009

Thank you Chairman Bendict and members of the Assembly Committee on Public Health for the opportunity to provide you with information regarding Assembly Bill 56; I am Tom Engels, Vice President of Public Affairs for the Pharmacy Society of Wisconsin. The Pharmacy Society of Wisconsin is the only organization in Wisconsin that solely represents the interests of Wisconsin pharmacists and pharmacy technicians.

2009 Assembly Bill 56 (AB 56) seeks to impose a limitation on the direct-to-consumer-advertisements of prescription medications by prohibiting in-state broadcasters and publishers distributing prescription drug advertisements. This legislation would not apply to advertisements generated from outside of Wisconsin and to information provided to a pharmacist by a manufacturer.

The extent of this legislation in Wisconsin would obviously be limited because a majority of the direct-consumer-advertising seen by Wisconsin consumers comes from outside of the state. However, this legislation does allow for the opportunity to discuss this practice and allow for information to be presented that can assist the committee. The Pharmacy Society of Wisconsin is testifying for information only, our organization has not taken a position on the legislation before you today.

Are Consumers Informed

Wisconsin health consumers are confronted with a wide variety of advertisements for the prescription drugs. Every day consumers are confronted with a barrage of advertisements on television, radio, newspaper, magazines and the Internet. Consumers, even those that consider themselves to be knowledgeable decision makers, may not be fully informed about advertisement for prescription drugs. For instance, the Food and Drug Administration has regulatory authority over prescription drug advertisements, but is not required to review any of the advertisements before they are placed. However, the FDA does investigate advertisements and may issue a warning letter when an advertisements is misleading.

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We have all seen these advertisements and maybe even been persuaded by the information being conveyed. A smiling man by the name of Bob becomes the envy of his neighborhood and coworkers because he can now perform. A bee flies about telling us about allergies or a human stomach checks out of the heartburn hotel. But how many of us can recall all the potential side effects which may occur but are quickly mentioned in the advertisements? Side effects such as; in some cases the use of this medication has caused uncontrolled bleeding and in rare cases death.

Direct-Consumer Advertisement is Big Business

Advertisements for brand name prescription medications are big business. An article published in the New England Journal of Medicine found total spending for pharmaceutical promotion grew from $11.4 billion in 1996 to $29.9 billion in 2005, an increase of 330 percent. But only 14 percent of the increase was dedicated to direct-consumer-advertising. Consumer Reports Adwatch found that in 2007 drug manufacturers spent over $5 billion on advertising.

For most Wisconsin consumers, their choice of prescription medications is based on an examination by their physician and a consultation with their pharmacist. These health consumers may see the advertisements but they do not allow their prescription decisions to be made based on a 30 second commercial or a glitzy print advertisement.

The Pros and Cons of Direct Consumer Advertising of Prescription Drugs

Studies have shown that most direct consumer advertising generally begins within one-year of the introduction of the drug. These advertisements can have both a positive and a negative affect on consumers. Studies have shown for some chronic diseases, under-use of medications was averted by advertisements. Conversely, studies have shown over-use of, medications have also occurred. A legitimate argument can be made that advertisements for prescription medication do provide some degree health education for consumers. There are some consumers that, because of an advertisement, sought medical attention and later received a prescription for the advertised drug; to these consumers the advertisement was of great benefit. But, these advertisements do influence consumer thinking and Wisconsin physicians and pharmacists alike can attest to patients that have demanded a certain prescription medication because of an advertisement.

Because direct-consumer-advertisements are only for the more expensive brand name drugs, consumers may be left with the impression that only these prescription drugs can help. In many cases there are generic medications available that are equally effective but are, more often than not, considerably less costly than the brand name medications. Patients should be apprised of all of their options and should not be limited based on the information from an advertisement. We recommend patients discuss their medications with their physician and pharmacist.

Food and Drug Administration

Since the policy to allow direct-consumer-advertisement was implemented, the FDA enforcement involvement has been questioned. Although the FDA has the authority to regulate the content of these advertisements but it has not been routinely done. In fact, there has been a significant FDA enforcement decline in recent years. The Wisconsin legislature could urge congressional action to require better enforcement by the FDA of advertisements.

In some cases drug manufacturers have voluntarily limited their direct consumer advertising campaigns. Some manufacturers, in order to allow time for health professionals, like pharmacists to be better educated on the drug's effects and to carefully monitor the medication for possible side effects that may not have been detected during clinical studies. This voluntary delay policy is supported by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Institute of Medicine which recommends restricting advertising for newer prescription drugs so all the effects can be determined. Vioxx, a drug that was heavily marketed to consumers, was later withdrawn by the manufacturer after significant side-effects were detected. Had a delay in advertising been in effect the problems associated with Vioxx may have been detected sooner.

Conclusion

Direct-consumer-advertising has been controversial since it was permitted in 1997. Since that time there have been calls for the regulation and out right elimination of these advertisements by consumers and health care professionals.

The Pharmacy Society of Wisconsin believes that health consumers should be well informed and should have access to information. But consumers should not base their prescription decisions solely on advertisements. We have always encouraged patients to talk with their pharmacist about their prescription medications.

Wisconsin health care consumers should be able to receive their prescription medications from the pharmacy of their choice and from the pharmacist they trust.

Thank you for this opportunity and I would be glad to answer any questions committee members may have.

WMC
WISCONSIN'S BUSINESS VOICE

To: Chairperson Chuck Benedict
Members of the Assembly Committee on Public Health
From: R.J. Pirlot, Director, Legislative Relations
Date: March 9, 2009
Subject: Opposition to Assembly Bill 56, which would ban in-state prescription drug advertising.

Assembly Bill 56 (AB 56) would prohibit advertising for prescription drugs. The prohibition would not apply to advertisements that are broadcast from, mailed from, or shipped from outside of Wisconsin. The prohibition would also not apply to advertisements sent directly to pharmacists or to practitioners who can prescribe prescription drugs. The Wisconsin Department of Agriculture, Trade and Consumer Protection in its analysis of AB 56 stated "[t]he department understands from communication with the sponsors, that this bill intends to only include advertisements, both print and broadcast, that both originate and terminate in Wisconsin. Based on this information the department is not aware of any advertising activity of this type that occurs in Wisconsin; therefore we do not believe there will be any fiscal effect on the department."

WMC opposes AB 56 and respectfully requests you oppose AB 56, too.

AB 56 would attempt to ban a form of commercial speech and, as such, run afoul of First Amendment freedom-of-speech protections. Companies, in general, have a constitutional right to disseminate information about legal products and, in the case of prescription drugs, which have been deemed safe to market by the United States Food and Drug Administration.

AB 56 proponents attempt to argue in-state prescription drug advertising jeopardizes public health, therefore commercial-speech restrictions are justified. WMC respectfully reminds the committee that no matter how much a consumer may want a certain prescription drug, it is only with a prescription from a practitioner that a consumer may actually legally obtain the drug in question. Practitioners with authority to prescribe prescription drugs would, as they should, continue to serve as the ultimate decision-maker regarding whether a consumer is able to access a particular drug.

WMC respectfully requests you oppose AB 56.

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State of Wisconsin
Jim Doyle, Governor

Department of Agriculture, Trade and Consumer Protection
Rod Nilsestuen, Secretary

March 10, 2009

Representative Chuck Benedict
Chair, Assembly Public Health Committee
Room 306 West, State Capitol
P.O. Box 8952
Madison, WI 53708

Re: AB 56 – Prescription Drug Advertising

Dear Representative Benedict:

Thank you for providing the Department of Agriculture, Trade & Consumer Protection the opportunity to present information regarding AB 56. The department has a number of concerns regarding the language of the bill. In our opinion, the bill, as currently written, will be difficult, if not impossible, to enforce because it permits a number of differing interpretations. This arises from a lack of definitions for a number of key words and phrases.

AB 56 prohibits advertising for prescription drugs. The proscription, however, is not absolute. Rather, a prescription drug ad is permitted if it, "is broadcast from or is mailed or shipped to the ultimate recipient of the advertisement from outside this state."

The bill provides no guidance on what "broadcast from outside this state" means. The following hypothetical demonstrates the problem caused by no definition. Assume CBS corporate in New York sends a tape of a prescription ad to its Madison affiliate and tells it to air the ad sometime during the 10 p.m. news. If the local CBS station complies, is the ad broadcast from inside or outside this state? What if the same ad is part of a CBS program, like 60 Minutes? Is the ad broadcast from inside or outside the state? The same questions apply to radio, satellite or cable broadcasts.

AB 56 also provides that a prescription drug ad is not prohibited if it is "mailed or shipped to the ultimate recipient of the advertisement from outside this state." What is the definition of "ultimate recipient"? The lack of definition again leads to problematic interpretations.

Another hypothetical: Newsweek ships its magazine from outside Wisconsin. In addition to shipping to individuals, it also ships to Walgreen's, Barnes & Noble, and other retailers that then sell them to individuals. If Walgreen's is considered the ultimate recipient, there is no violation because the Walgreen's and the individual purchaser are both in the state. However, if the person who is going to buy and read the magazine is the ultimate recipient, then shipping them to Walgreen's, even from outside the state is a violation. Which scenario do the drafters intend? Both are legally plausible.

With respect to the "shipped . . . from outside the state" exception to the advertising prohibition, we understand that many national periodicals and newspapers are printed and shipped by businesses that are located in Wisconsin, e.g.., Quad/Graphics. Some of these periodicals are shipped to Wisconsin residents. If the magazine publisher is outside Wisconsin, but the magazine printed in the state and mailed from within the state to a state resident, is there a violation because the shipper and the subscriber are both in the state? Again, a lack of definitions makes several different interpretations plausible.

(Also, while not a consumer protection issue, it strikes us that this bill may very well harm Wisconsin businesses like Quad/Graphics because the NY Times or Newsweek might move their contracts w/ businesses like Quad/Graphics to similar out-of state businesses to ensure compliance with the provisions of this bill.)

Finally, no penalty is specified in the bill. The default is a criminal penalty under Sec. 100.26 (1), Stats., of up to a $200 fine and/or 6 mos. in jail. One can't put a corporation in jail so a fine is the penalty. How many $200 fines can one impose on an advertiser that violates the provisions of this bill by shipping 5,000 copies at one time from inside the state to a Wisconsin resident - $200 or $1million?

In sum, the current draft of the bill creates a variety of enforcement difficulties due to a lack of definitions. If definitions were added or if the language were clarified in some other fashion, these difficulties might cease to exist.

Again, thank you for allowing us to provide written testimony for information on AB 56.

Respectfully,

Janet Jenkins
Administrator
Division of Trade and Consumer Protection

Wisconsin Society of Podiatric Medicine, Inc.

Memo

TO: **Assembly Committee on Public Health**

FROM: **Dr. Bob Sage, President, and Dr. Mike Thompson, Legislative Chair**

CC: **Matt Moroney and Tony Driessen, DeWitt Ross & Stevens**

RE: **Support for AB-44**

DATE: **March 10, 2009**

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On behalf of the Wisconsin Society of Podiatric Medicine, we are writing to ***support the passage of AB-44 with an amendment to grant podiatrists the ability to become a volunteer health care provider.*** We believe it is appropriate for podiatrists to be able to participate in this valuable program based on their specialty area of practice, their education, and the range of patients who typically seek treatment from a podiatrist.

A podiatrist is a Doctor of Podiatric Medicine (DPM), also known as a podiatric physician or surgeon, qualified by their education and training to diagnose and treat conditions affecting the foot, ankle and related structures of the leg. Podiatrists are uniquely qualified among medical professionals to treat the foot and ankle based on their education, training and experience. Podiatric patients range from newborns and infants to the geriatric.

A licensed podiatrist must fulfill 3 to 4 years of undergraduate study and then complete a 4-year academic Podiatric degree program to acquire a Doctor of Podiatric Medicine degree. The first two years are primarily classroom and laboratory instruction, and the last two include more clinical rotations and practical experience. By graduation, the podiatrist has also completed National Board examinations to establish that he or she maintains a level of competency to practice. The podiatrist must then take a minimum of 2 years of postgraduate training ("Residency") before applying for a license to practice podiatric medicine and surgery in Wisconsin. To maintain a Wisconsin license, a podiatrist must continue to take at least 50 hours of continuing medical education acceptable to the Podiatrists Affiliated Credentialing Board every two years.

As you can see, nonprofit agencies, elementary schools and their constituencies will benefit from podiatrists who desire to participate in the Volunteer Health Care Provider Program.

Thank you for your consideration.